

- B' contd
170. The kit of claim 165 where the therapeutic effect is antianginal.
171. The kit of claim 165 where the therapeutic effect is cardiac risk management.
172. The kit of claim 165 where the therapeutic effect is antiatherosclerotic.

REMARKS

Upon entry of the Amendment, the claims will be 1 - 3 and 84 - 172.

The January 4, 2001 Office Action made restriction and election of species requirements to which applicants respond as follows:

Claims 4-15 (invention II), 16-27 (invention III), 28-71 (invention IV) and 72-83 (invention V) have been cancelled. Applicants reserve the right to present some or all of these claims in one or more continuing (i.e., divisional) applications, and the cancellation is without prejudice to applicants' right to prosecute claims to such invention(s) in other applications. Further comment as to these inventions is unnecessary at this time.

As required, applicants hereby elect, with traverse, invention VII (original claims 99-117) drawn to methods of treatment. Further, as required, applicants elect for further prosecution the species of achieving an antihypertensive and an antihyperlipidemic effect in the mammal being treated. Regarding this election of species, it is understood that upon allowance of a generic claim, the remaining species will be considered in accord with 37 C.F.R. 1.141. Original claims presently pending which read on this elected species within elected invention VII are Nos. 99-108 and 112-114. Newly added claims 120 and 121-144 also read on invention VII and the elected species.

Applicants traverse the restriction among inventions I, VI and VII (the remaining invention categories) because these three sets of claims are all closely related and traditionally have been examined together and are issued routinely by the PTO in a single patent. Thus, original claims 1-3

(invention I), 84-98 (invention VI) and 99-117 (invention VII) all recite, in dosage form, kit form or method of treatment format respectively, the discovery of the joint use of amlodipine (and its salts) and atorvastatin (and its salts) as therapy for a variety of medical conditions. The common theme regarding these three claim categories is the amlodipine/atorvastatin combination, whether defined as a combination per se, a kit containing the two active ingredients or a method for therapeutic treatment. Given this common thread, it is believed that the examination of all three inventions will not unduly burden the Office and standard practice within the PTO is to examine and issue these three kinds of claims in a single patent.

New claims 118-172 have been added. Regarding inventions designated as I, VI and VII, the new claims can be grouped as follows, but applicants respectfully submit that all should be examined together.

Group I	claim 118
Group VI	claims 119 and 165 - 172
Group VII	claims 120 - 164

The newly added claims are in a slightly revised format but are fully supported in the specification and the original claims as filed.

Claims 121-132 are broad method claims, with independent claims 121 and 127 being supported by original claim 99 and the disclosure at pages 6 et seq "Summary Of The Invention", in particular pages 17-19 and the examples at pages 23-32. In pages 23-32, applicants describe, inter alia, specific studies which begin with examination of "Entry criteria", i.e., the patient population is examined by trained personnel to determine whether its members would benefit from the treatment in question. Assuming that a patient is so evaluated and diagnosed, then therapy by the recited

combination is administered to that patient. Dependent claims 122 - 126 and 128-132 are supported by original claims 100-103.

Claims 133-138 are directed to combined treatment for hypertension and hyperlipidemia and are supported as above with special reference to pages 28-30 of the specification.

Claims 139 - 144 (cardiac risk) are similarly supported with special reference to pages 30-32 of the specification.

Claims 145-150 (angina) are similarly supported (see especially pages 26-28).

Claims 151 - 164 (atherosclerosis) are supported in the same manner, in particular pages 23-26 and, for example, original claims 31-38.

Claims 165 - 172 drawn to a kit are supported by original claims 84-98, especially page 34 of the specification which indicates that the kit "includes directions".

No fee is believed to be due for the additional claims. If the undersigned is in error, please debit any fees to Deposit Account 03 - 2775.

No extension of time is believed to be due for responding the Official Action. If the undersigned is in error, an extension of time is respectfully requested and the Office should debit any associated fees to Deposit Account 03 - 2775.

A prompt and favorable response is earnestly solicited.

Respectfully submitted,
CONNOLLY BOVE LODGE & HUTZ LLP

By 

Rudolf E. Hutz, Reg. 22,397

1220 Market Street

P. O. Box 2207

Wilmington, DE 19899

(302) 658-9141

Dated: February 5, 2001

::ODMA\MHODMA\CB;128619;1